Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2013

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Abstract: Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the post-market environmental monitoring (PMEM) report for the 2013 growing season of maize MON 810 provided by Monsanto Europe S.A. The EFSA GMO Panel concludes that the data related to insect resistance monitoring does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain over the 2013 growing season. However, considering that the methodology for insect resistance monitoring remained unchanged compared to previous PMEM reports, the EFSA GMO Panel reiterates its previous recommendations for improvement of the insect resistance management plan of maize MON 810. The EFSA GMO Panel also recommends, as part of general surveillance, the continuation of the screening and discussion of literature on possible adverse effects of maize MON 810 on rove beetles. In the absence of information on the general surveillance of maize MON 810 in 2013, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013, or on possible changes to the methodology as compared to previous growing seasons.

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SCIENTIFIC OPINION

Scientific Opinion on the annual post-market environmental monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON 810 in 2013[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2,3]

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ABSTRACT

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the post-market environmental monitoring (PMEM) report for the 2013 growing season of maize MON 810 provided by Monsanto Europe S.A. The EFSA GMO Panel concludes that the data related to insect resistance monitoring does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain over the 2013 growing season. However, considering that the methodology for insect resistance monitoring remained unchanged compared to previous PMEM reports, the EFSA GMO Panel reiterates its previous recommendations for improvement of the insect resistance management plan of maize MON 810. The EFSA GMO Panel also recommends, as part of general surveillance, the continuation of the screening and discussion of literature on possible adverse effects of maize MON 810 on rove beetles. In the absence of information on the general surveillance of maize MON 810 in 2013, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013, or on possible changes to the methodology as compared to previous growing seasons.

KEY WORDS

Annual PMEM report, cultivation, case-specific monitoring, insect resistance monitoring, maize, MON 810

[1] On request from the European Commission, Question No EFSA-Q-2014-00856, adopted on 4 March 2015.

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SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the post-market environmental monitoring (PMEM) report for the 2013 growing season of maize MON 810 provided by Monsanto Europe S.A.

In the absence of information on the general surveillance of maize MON 810 over the 2013 growing season, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013, or on possible changes to the methodology as compared to previous growing seasons. However, the EFSA GMO Panel reiterates all its previous recommendations pertaining to the general surveillance of maize MON 810 for consideration by the applicant.

The EFSA GMO Panel focused its assessment on the novel 2013 datasets (i.e. data from monitoring changes in baseline susceptibility of target pests, information on refugia compliance in Spain and Portugal, and outcomes of the literature review on possible adverse effects of maize MON 810 on rove beetles). The EFSA GMO Panel concludes that the 2013 data analysis does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab in Spain over the 2013 growing season. Considering that the methodology for insect resistance monitoring remained unchanged compared to previous PMEM reports, the EFSA GMO Panel reiterates its previous recommendations for improvement of the insect resistance management plan of maize MON 810, in particular the recommendation for annual sampling of both bi-/multi-voltine target pests in areas where maize MON 810 adoption rate is $\geq$ 50%.

The EFSA GMO Panel also recommends, as part of general surveillance, the continuation of the screening and discussion of literature on possible adverse effects of maize MON 810 on rove beetles.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

The marketing of maize MON 810 (notification C/F/95/12-02) was authorised under Directive 90/220/EEC[4] in the European Union (EU) for all, other than food, uses by the Commission Decision 98/294/EC[5] of 22 April 1998. Consent was granted to the applicant (Monsanto Europe S.A.) by France on 3 August 1998. Food uses of maize derivatives were notified according to Article 5 of the Novel Food Regulation (EC) No 258/97[6] on 6 February 1998.

On 15 June 2009, the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (hereafter referred to as EFSA GMO Panel) issued a scientific opinion on the renewal of the authorisation for the continued marketing of: (1) existing food and food ingredients produced from maize MON 810; (2) feed consisting of and/or containing maize MON 810, including the use of seed for cultivation; and (3) food and feed additives, and feed materials produced from maize MON 810. The EFSA GMO Panel concluded that 'maize MON 810 is as safe as its conventional counterpart with respect to potential effects on human and animal health', and that 'maize MON 810 is unlikely to have any adverse effect on the environment in the context of its intended uses, especially if appropriate management measures are put in place in order to mitigate possible exposure of non-target (NT) Lepidoptera'. The EFSA GMO Panel recommended that 'especially in areas of abundance of non-target Lepidoptera populations, the adoption of the cultivation of maize MON 810 be accompanied by management measures in order to mitigate the possible exposure of these species to maize MON 810 pollen'. In addition, the EFSA GMO Panel advised that 'resistance management strategies continue to be employed and that the evolution of resistance in lepidopteran target pests continues to be monitored, in order to detect potential changes in resistance levels in pest populations' (EFSA, 2009).

The EFSA GMO Panel further supplemented its risk assessment conclusions and risk management recommendations on non-target Lepidoptera exposed to genetically modified (GM) maize pollen by reapplying the mathematical model developed by Perry et al. (2010, 2011, 2012). The EFSA GMO Panel also provides additional information on the factors affecting the insect resistance management (IRM) strategy (EFSA Panel on Genetically Modified Organisms, 2011b, 2012d).

From 2005 onwards, the applicant submitted to the European Commission its annual post-market environmental monitoring (PMEM) reports on the cultivation of maize MON 810.

Since 2010, the European Commission asked the EFSA GMO Panel to assess the PMEM reports submitted by Monsanto on the cultivation of maize MON 810. The EFSA GMO Panel therefore adopted a scientific opinion on the 2009, 2010, 2011 and 2012 PMEM reports (EFSA GMO Panel, 2011b, 2012a, 2013, 2014). From the data provided in those reports, the EFSA GMO Panel did not identify adverse effects on the environment, human and animal health due to maize MON 810 cultivation. However, the EFSA GMO Panel noted shortcomings in the methodology and hence made recommendations for improvement of the PMEM of maize MON 810.

On 14 November 2014, the EFSA GMO Panel received from the European Commission a request to assess the PMEM report submitted by Monsanto on the cultivation of maize MON 810 in 2013.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION AND EFSA

The European Commission asked the EFSA GMO Panel 'to evaluate the findings of the monitoring activities, taking into consideration the comments received from Member States and to assess the appropriateness of the methodology if this is found to differ compared to the previous season'.

[4] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. OJ L 117, 8.5.1990, p. 15–27.
[5] Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON810), pursuant to Council Directive 90/220/EEC (98/294/EC). OJ L 131, 5.5.1998, p. 32–33.
[6] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–9.

ASSESSMENT

1. Introduction

Upon request of the European Commission, the EFSA GMO Panel assessed the PMEM report[7] on the 2013 growing season of maize MON 810 (hereafter referred to as '2013 PMEM report') taking into consideration the comments received from Member States on the 2013 PMEM report.

In 2013, maize MON 810 was cultivated in the Czech Republic (2560 ha), Portugal (8202 ha), Romania (835 ha), Slovakia (100 ha) and Spain (136 962 ha) over a total area of approximately 148 659 hectares.

2. Overview of information provided by the applicant

The 2013 PMEM report differs from previous reports as the applicant did not report on the general surveillance of maize MON 810 during the 2013 growing season. In contrast to its previous reports, the applicant did not submit the raw data from the survey of farmers who cultivated maize MON 810 in 2013, nor an overview of the scientific papers on maize MON 810 or the related insecticidal Cry1Ab protein published between June 2013 and June 2014.

The applicant reported on the outcomes of:

- the insect resistance management (IRM) plan[8] consisting of: (1) the 'high dose-refuge' strategy, including surveys[9] on farmers' compliance with non-Bt refugia; (2) the monitoring for changes in baseline susceptibility of target pests and the diagnostic dose[10] (DD) assays[11]; (3) a communication and education plan of farmers; (4) a remedial action plan in the event of any confirmed evolution of pest resistance;
- the company stewardship activities;
- the search for publications related to possible adverse effects of maize MON 810 on rove beetles (Coleoptera: Staphylinidae) as follow-up to a previous recommendation of the EFSA GMO Panel (EFSA, 2014).

Based on the weight of evidence available, the applicant concluded that: (1) 'there are no adverse effects attributed to the cultivation of maize MON 810 in Europe', and that (2) 'the result of 2013 monitoring concurs with the results observed since monitoring was started in 2003'.

3. Assessment

In the absence of information on the general surveillance of maize MON 810 over the 2013 growing season, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013. The EFSA GMO Panel is therefore not in the position to conclude on possible changes to the methodology followed by the applicant as compared to previous growing seasons. However, the EFSA GMO Panel reiterates all its previous recommendations pertaining to the general surveillance of maize MON 810 for consideration by the applicant (EFSA GMO Panel, 2011b, 2012a, 2013, 2014).

[7] The 2013 PMEM report is published online: http://ec.europa.eu/food/plant/gmo/reports_studies/report_2013_mon_810_en.htm
[8] 2013 PMEM report, Appendix 1.
[9] 2013 PMEM report, Appendix 2.
[10] The diagnostic dose (DD) is the dose that causes 99% of moulting inhibition to first instar larvae (MIC_{99}).
[11] 2013 PMEM report, Appendices 3 and 4.

In this scientific opinion, the EFSA GMO Panel focused its assessment on the novel datasets as provided in the 2013 PMEM report, i.e.

(1) the survey[12] carried out by the applicant to check farmers compliance with non-Bt refugia implementation in the five EU countries where maize MON 810 was cultivated in 2013;

(2) the report by Portuguese authorities on farmers compliance with non-Bt refugia implementation over the 2013 growing season;

(3) Spanish data[13] from monitoring changes in baseline susceptibility of target pests (i.e. European corn borer (ECB; *Ostrinia nubilalis* Hübner) and Mediterranean corn borer (MCB; *Sesamia nonagrioides* Lefebvre)) in 2013, and the assays with the DD;

(4) the overview and analysis of publications related to possible adverse effects of maize MON 810 on rove beetles.

Following the terms of reference of the mandate from the European Commission, the EFSA GMO Panel also considered whether the methodology used by the applicant to monitor maize MON 810 over the 2013 growing season differs from the methodology applied by the applicant in its PMEM reports for the 2009, 2010, 2011 and 2012 growing seasons of maize MON 810 (EFSA GMO Panel, 2011b, 2012a, 2013, 2014).

3.1. Implementation of non-Bt refugia

The EFSA GMO Panel analysed the results of the farmer survey addressing the implementation of non-Bt refugia. The applicant asked 256 farmers from four EU countries where maize MON 810 was cultivated in 2013 (Czech Republic, Romania, Portugal and Spain), to compile a questionnaire on the planting of non-Bt refugia. In Czech Republic, Portugal, and Romania, all farmers surveyed (66 in total) confirmed that non-Bt refugia were planted. In Spain, 12.5% of the farmers surveyed (190 in total) did not plant a refuge area even though there were required to. They provided the following two reasons for not planting a refuge area: (1) farmers were not informed about technical guidelines, and (2) the sowing is easier without the refuge area.

The results of the Spanish farmer's survey could not be corroborated to a similar study carried out by ANTAMA, the Spanish Foundation supporting the use of new technologies in agriculture, as provided in previous PMEM reports.

In 2013, the Portuguese authorities carried out an independent survey of 113 farmers (out of the 232 notifications received in 2013) cultivating maize MON 810 for control of good implementation of Portuguese law pertaining to cultivation of GM varieties. They concluded that there was full compliance with refuge implementation.

The 2013 PMEM report shows partial compliance with the implementation of non-Bt refugia in Spain. The EFSA GMO Panel therefore recommends that the applicant should maintain its efforts to increase the level of compliance, especially in regions of high maize MON 810 uptake. In this context, the education and training program of the farming community in managing maize MON 810 as proposed by the applicant is paramount.

3.2. Monitoring for changes in baseline susceptibility of target pests

The applicant monitored possible changes in baseline susceptibility of the target pests to Cry1Ab protein in North-East Spain (for both ECB and MCB) and Central Spain (for ECB only) by measuring the Moulting Inhibiting Concentrations (MIC_{50} and MIC_{90}). The applicant concluded that 'differences found in the susceptibility to the toxin are within the range of variability expected for field collections of these corn borers. Further, the analyses of historical series of susceptibility data of *S. nonagrioides*

[12] 2013 PMEM report, Appendix 2
[13] 2013 PMEM report, Appendices 3 and 4

or *O. nubilalis* to Cry1Ab did not reveal signs of changed susceptibility to this toxin by field collections from the sampling the areas considered'.

In the 2013 PMEM report, only MIC values were provided. Even though MIC values are more sensitive and precise than LC[14] values, the EFSA GMO Panel reiterates its previous recommendation to provide both LC and MIC values in future PMEM reports (EFSA GMO Panel, 2012).

As part of the harmonised IRM plan,[15] the applicant proposed to sample multivoltine target pest populations every two years in areas where maize MON 810 adoption rate varies between 20% and 80% of the total maize cultivated area. Annual sampling is foreseen only in exceptional circumstances in areas of high uptake (i.e. > 80% and therefore in areas where non-Bt refugia have not been implemented). In order to ensure an early detection of change in susceptibility of the ECB and MCB field populations, the EFSA GMO Panel reiterates its previous recommendation for annual sampling of both bi-/multi-voltine target pests in areas where maize MON 810 adoption rate is ≥ 50% (see Table 1 in EFSA, 2014).

The EFSA GMO Panel noted that a new Cry1Ab toxin batch was used for bioassays with ECB in 2013. The applicant verified the biological activity of the batches of protein used in the bioassays with field populations and concluded that the old toxin batch, used in 2011, and the new toxin batch, used in 2013, have similar biological activity.

The EFSA GMO Panel evaluated how the applicant addressed its previous recommendation to further investigate the stability and quality of the reference laboratory strain of *O. nubilalis* (for further details, EFSA GMO Panel, 2014). In its 2013 PMEM report, the applicant did not explicitly discuss the stability and quality of the reference laboratory strain, although some information regarding such matter can be extracted from Appendices 3 and 4. According to the applicant,[16] the reference laboratory strain of *O. nubilalis* that have been used in the bioassays since 2011 (namely G.04) seems to present egg-masses of good quality and adults of normal size. These parameters could indicate that the fitness of such strain was not reduced. However, experimental data corroborating such statement are not given (e.g. fitness parameters across generations, such as developmental time, pupal weight, fecundity, fertility). In addition, PCR analysis provided by the applicant showed that the strain G.04 is not infected by Nosema, a known pathogen of *O. nubilalis*. The applicant checked the quality of the reference laboratory strain which demonstrated acceptable performance in bioassays in 2013.

During the assessment of the 2012 PMEM report, a specific analysis[17] carried out by the French Haut Conseil des Biotechnologies (HCB) suggested a hypothesised increased tolerance of target pests in Spain when compared with the reference laboratory strain (EFSA, 2014). This could be explained by e.g.: (1) any type of change in the insecticidal Cry1Ab protein attributed to target pests (e.g. more or less toxic); (2) a modification (e.g. weakening) of the reference laboratory strain; and (3) an increased tolerance of the Spanish target pest populations to the Cry1Ab protein. The 2013 data for ECB do not confirm the assumption of increased tolerance of target pests to Cry1Ab protein in Spain (see Table 1).

[14] Lethal concentrations (LC).
[15] 2013 PMEM report, see Table 4 in Appendix 1.
[16] 2013 PMEM report, Appendix 4.
[17] Available at : http://www.hautconseildesbiotechnologies.fr/IMG/pdf/131108_Surveillance_mais_MON810_2012_Commentaires_CS_HCB.pdf

Table 1: Resistance ratios[18] of *Ostrinia nubilalis* populations sampled in 2009, 2011 and 2013

Population	Season	Toxin batch[1]	MIC50	MIC90	Resistance ratio MIC50	Resistance ratio MIC90
North-East Iberia	2009	B1	6.40	13.68	1.75	1.40
	2011	B2	1.79	4.19	0.29	0.24
	2013	B3	2.48	5.41	1.26	0.82
Central Iberia	2009	B1	3.09	11.98	0.85	1.25
	2011	B2	1.56	4.04	0.26	0.23
	2013	B3	2.40	6.38	1.22	0.97
Laboratory	2009	B1	3.65	9.56		
	2011	B2	6.08	17.43		
	2013	B3	1.96	6.57		

[1] Data provided by the applicant showed that the Cry1Ab toxin batches B1 and B2, and B2 and B3 have similar biological activity.

The MIC_{50} and MIC_{90} values reported in 2013 for MCB are in the range of those obtained in previous years. The EFSA GMO Panel concludes that the 2013 data analysis does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain (see Table 2).

Table 2: Resistance ratios[19] of *Sesamia nonagrioides* populations sampled in 2007, 2009, 2011 and 2013

Population	Season	Toxin batch	MIC_{50}	MIC_{90}	Resistance ratio MIC_{50}	Resistance ratio MIC_{90}
North-East Iberia	2007	B1	14	99	0.87	1.05
	2009	B1	22	188	1.16	1.56
	2011	B2	20	135	2.22	1.98
	2013	B2	19	163	2.7	3.39
Reference laboratory strain	2007	B1	16	94		
	2009	B1	19	120		
	2011	B2	9	68		
	2013	B2	7	48		

Moreover, the EFSA GMO Panel already advised that, once regular measurement of the susceptibility baseline is implemented, changes in the frequency of resistance alleles should also be reported (EFSA, 2013). The EFSA GMO Panel therefore welcomes the preliminary assay provided by the applicant based on the DD and encourages him to provide DD assays in future PMEM reports. However, further details on the methodology (e.g. number of individuals tested) should be provided for sake of an appropriate assessment of the results.

3.3. Analysis of papers on possible effects of maize MON 810 on rove beetles

In response to a previous recommendation from the EFSA GMO Panel (EFSA GMO Panel, 2014), the applicant listed and analysed relevant publications (Albajes et al., 2012, 2013; Comas et al., 2014;

[18] The resistance ratio is calculated between susceptibility values for O. nubilalis collected from North-East and Central Iberia and for the susceptible laboratory strain for each growing season.

[19] The resistance ratio is calculated between susceptibility values for S. nonagrioides collected from North-East Iberia and for the susceptible laboratory strain for each growing season.

Twardowski et al., 2014) related to possible adverse effects of maize MON 810 on rove beetles. Based on the aforementioned publications, the specificity of the Cry1Ab protein to Lepidoptera, and the heterogenous distribution of rove beetles in maize fields, the applicant concluded that the observed difference in rove beetles abundance in maize MON 810 fields reported by Albajes et al. (2012) are unlikely to be attributed to the Cry1Ab protein.

Considering various data reporting the highly variable distribution of rove beetles over time and space (e.g. de la Poza et al., 2005; Balog et al., 2010), the EFSA GMO Panel recommends, as part of general surveillance, the continuation of the literature screening and discussion of literature on possible adverse effects of maize MON 810 on rove beetles.

4. Conclusions and recommendations

In the absence of information on the general surveillance of maize MON 810 over the 2013 growing season, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013, or on possible changes to the methodology as compared to previous growing seasons. However, the EFSA GMO Panel reiterates all its previous recommendations pertaining to the general surveillance of maize MON 810 for consideration by the applicant (EFSA GMO Panel, 2011b, 2012a, 2013, 2014).

The EFSA GMO Panel focused its assessment on the novel 2013 datasets (i.e. data from monitoring changes in baseline susceptibility of target pests, information on refugia compliance in Spain and Portugal, and outcomes of the literature review on possible adverse effects of maize MON 810 on rove beetles). The EFSA GMO Panel concludes that the 2013 data analysis does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain over the 2013 growing season. Considering that the methodology for insect resistance monitoring remained unchanged compared to previous reports, the EFSA GMO Panel reiterates its previous recommendations for improvement of the insect resistance management plan of maize MON 810, in particular the recommendation for annual sampling of both bi-/multi-voltine target pests in areas where maize MON 810 adoption rate is $\geq$ 50%.

The EFSA GMO Panel also recommends, as part of general surveillance, the continuation of the screening and discussion of literature on possible adverse effects of maize MON 810 on rove beetles.

OVERALL CONCLUSIONS AND RECOMMENDATIONS

In the absence of information on the general surveillance of maize MON 810 over the 2013 growing season, the EFSA GMO Panel cannot conclude on potential unanticipated adverse effects due to the cultivation of maize MON 810 in 2013 or on possible changes to the methodology as compared to previous growing seasons.

The data related to insect resistance management, submitted by the applicant in its 2013 PMEM report, does not indicate a significant and consistent decrease in susceptibility of the target pest field populations to Cry1Ab protein in Spain over the 2013 growing season.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 13 November 2014, to the EFSA Executive Director requesting the assessment of the MON 810 monitoring report for the 2013 cultivation season provided by Monsanto; the 2013 PMEM report was annexed to the letter.

2. Comments from Member States on the PMEM report for cultivation of maize MON 810 in 2013.

3. Acknowledgement letter, dated 1 December 2014, from the EFSA Executive Director to the European Commission.

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